Response to Elliot and Crew (DOI: 10.1089/neu.2018.5697) Response to Christison et al. (DOI: 10.1089/neu.2017.5413): Intermittent Catheterization: The Devil Is in the Details

Walter, Matthias ; Christison, Kathleen ; Wyndaele, Jean-Jacques J M ; Kennelly, Michael ; Kessler, Thomas M ; Noonan, Vanessa K ; Fallah, Nader ; Krassioukov, Andrei V

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Letter to the Editor:

Response to Elliot and Crew (DOI: 10.1089/neu.2018.5697) Response to Christison et al. (DOI: 10.1089/neu.2017.5413): Intermittent Catheterization: The Devil Is in the Details

Authors:

Matthias Walter[1], mwalter@icord.org

Kathleen Christison[1], k.christison@alumni.ubc.ca

Jean-Jacques J.M. Wyndaele[2], wyndaelejj@skynet.be

Michael Kennelly[3], Michael.Kennelly@atriumhealth.org

Thomas M. Kessler[4], tkessler@gmx.ch

Vanessa K. Noonan[5], vnoonan@rickhanseninstitute.org

Nader Fallah[5,6], nfallah@rickhanseninstitute.org

Andrei V. Krassioukov[1,7,8†] (please see below)

Affiliations:

[1] International Collaboration on Repair Discoveries (ICORD), Faculty of Medicine (FoM), University of British Columbia (UBC), Vancouver, British Columbia (BC), Canada

[2] Department of Urology, University of Antwerp, Antwerp, Belgium

[3] Department of Urology, Carolinas Medical Center, Charlotte, NC, USA

[4] Department of Neuro-Urology, Balgrist University Hospital, University of Zürich, Zürich, Switzerland

[5] Rick Hansen Institute, Vancouver, BC, Canada

[6] Division of Neurology, Department of Medicine, FoM, UBC, Vancouver, BC, Canada

[7] Division of Physical Medicine and Rehabilitation, Department of Medicine, FoM, UBC, Vancouver, BC, Canada

[8] G.F. Strong Rehabilitation Centre, Vancouver, BC, Canada

Journal of Neurotrauma
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† **Corresponding author:**

Andrei V. Krassioukov, MD, PhD, FRCPC

ICORD, 818 West 10th Avenue

Vancouver, BC, Canada, V5Z 1M9

E-mail: krassioukov@icord.org

Phone: 605 675 8819

Fax: 604 675 8820

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Dear Editor,

We would like to thank Drs. Elliott and Crew for their attention to and comments on our short communication entitled "*Intermittent Catheterization: The Devil Is in the Details.*"**[1]** We are thankful for the opportunity to address the concerns raised by the authors. We appreciate that Drs. Elliott and Crew agree (with our report) on the fact that the Cochrane review by Prieto et al. ('Intermittent catheterisation for long-term bladder management') had data extraction discrepancies.**[2]** Furthermore, based on Drs. Elliott and Crew's Letter to the Editor, they did not have any concerns with respect to our analysis that were performed following corrections of data extractions and applying an more recent and appropriate definition of the UTI.**[3]**

At the same time Drs. Elliott and Crew raised concerns with our assertions of the data. In particular, they indicated that our abstract's statement "our analysis revealed a trend to favor single over multiple use of catheters", was not supported by data presented in our analyses. Furthermore, Drs. Elliott and Crew refer to a "trend" is usually reserved in scientific literature to identify something that almost reaches statistical significance but falls just short ($p<0.10$)" and point out to a p-value of 0.59. We would like to indicate that in our manuscript we never used the word "trend" with the intention as something close to being statistically significant (as suspected by Drs. Elliott and Crew). We used the term "trend" to indicate that the result of Analysis 2.2, i.e. figure 1E [risk ratio 0.7 (95% CI 0.24 – 3.05)] is in favor of single use catheter with fewer incidence of UTI compared to multiple use (5/71, 7% vs. 7/69, 10%). To be correct, the p-value for figure 1E is 0.512 indicated in our manuscript, while Drs. Elliott and Crew stated that this value is 0.59, which is actually the p-value from figure 1B. Furthermore, we also correctly stated in the figure legend, "*only three trials were included in this analysis. Applying the M-H method (fixed effect model) for meta-analysis did not show a significant difference (p=0.512) between both techniques with regards to the incidence of UTI. Given the small number of participants (n=140) and short duration of investigation (maximum 8 weeks), no final conclusion can be drawn*." Furthermore, we stated in the discussion section "*until evidence can confidently demonstrate that multiple use is as safe as single use of catheters, healthcare providers should advocate a single use of catheters in individuals with spinal cord injury*". Drs. Elliott and Crew comment on this with "is also faulty based on the evidence provided in their

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meta-analysis and given that single use catheterization only became a standard in the last decade due to the voice of "expert" opinion (not data)." However, we believe that our statement is correct and we can provide the appropriate evidence for that:

1. Evidence on single use of catheters for intermittent catheterization in Europe: Single-use catheterization has been established in Europe (e.g. Sweden) since the 1990's and not due to "expert" opinions but because of data (e.g. Waller et al.).**[4]** Hakansson, state in his review that "The literature supports the use of single-use hydrophilic catheters to reduce the risk of urethral trauma and urinary tract infection with a reported incidence of the latter between 40 and 60%, as compared with 70-80% for reuse catheters" and concluded "Complications associated with reuse need to be further investigated. Although awaiting evidence, it is recommended to use a confirmed safe, patient-preferred, noninfecting and nontraumatic technique for intermittent catheterization."**[5]** Furthermore, The National Institute for Health and Care Excellence (NICE) guidelines [https://www.nice.org.uk/guidance/cg139/chapter/2-Research-recommendations] with regards to the re-use of catheters state that "In order to make an 'off-licence' recommendation for the use of these catheters, better quality evidence is needed." Even in the healthiest subgroup of individuals with SCI, i.e. elite athletes, a link between the reuse of catheters and more frequent UTIs was reported.**[6]**
2. Evidence on single use of catheters for intermittent catheterization in the US: In 2011, Newman and Wilson from the Society of Urologic Nurses and Associates clearly stated that the re-use of catheters is considered "off label".**[7]** In addition, the authors proposed in their "Review of Intermittent Catheterization and Current Best Practices" (I) the use of a new catheter at every occasion of intermittent catheterization to prevent UTI, (II) to consider a hydrophilic catheter to prevent UTI in the case of traumatic catheterization and (III) a single-use/closed system to prevent UTI in the case of poor catheterization technique and catheter care.**[7]** Furthermore, The Infectious Disease Society of America's guideline from 2009 concluded that the evidence is poor to moderate for recommending multiple-use catheters instead of sterile single-use catheters with regard to bacteriuria or UTI and that there are insufficient data for recommending a cleaning method for multiple-use catheters.**[3]**

Journal of Neurotrauma
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3. Legal position on urethral catheters as medical devices: The US Food and Drug Administration (FDA) [https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf] as well as the Australian Therapeutic Goods Administration (TGA) [https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd] require the same quality, performance and safety on reused devices as for original single-use devices. However, none of the commercially available catheters have FDA or TGA approval for re-use. Given this legal position, there is no basis to recommend the re-use of catheters. Furthermore, with the above-mentioned legal position, any patient could be held liable to any complications arising from multiple use of catheters. Given the fact that most patients are not advised on this legal position, any attempt to recommend re-use of catheters could be considered as unethical. Moreover, we would like to highlight that there are neither standards nor generally accepted consensus / guideline statements on how to clean and store catheters for multiple use. Importantly, there is a complete lack of high-level evidence on these essential topics. Currently there are limited randomized control trials (RCTs) evaluating single vs multiple use of catheters for long-term bladder management in SCI. Together with available data from mostly observational studies and principles of infection control, the support of single-use catheterization is necessary. Considering these limitations, further research to elucidate high-grade recommendations is required.

Finally, Drs. Elliott and Crew recommended that much like the original Cochrane Review our current abstract should be retracted. Referring to our previous arguments, we do not see any reason to withdraw our abstract, since it is neither misleading nor the only source of our research. To allow everyone to read the entire work, we published our manuscript as an open-access article.**[1]**

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